510(k) Summary of Safety and Effectiveness

K082990

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
August 11, 2008

NOV 20 2008

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Tristan Choi, Program Manager
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	XELIS™
Common Name:	Picture Archiving Communications System
Classification Name:	system, image processing, radiological
Product code:	LLZ
Device Classification:	892.2050

Predicate Device: 21 CFR 807. 92(a)(3)

	K041761	K052545
Device Classification Name	system, image processing, radiological	system, image processing, radiological
Device Name	RAPIDIACOLON	INFINITT G3 PACS
Applicant	INFINITT CO., LTD.	INFINITT CO., LTD.
Regulation Number	892.2050	892.2050
Classification Product Code	LLZ	LLZ
Decision Date	07/13/2004	11/08/2005
Classification Advisory Committee	Radiology	Radiology

Device Description: 21 CFR 807 92(a)(4)

XELIS is a CT colonography dedicated workstation designed to help radiologists to examine images. XELIS receives DICOM compliant CT images from a remote PACS server. Both primary 2D and primary 3D review modes are supported to meet the various needs of users.

- Real-time and one-pass navigation based on an unfolded view to show complex inner wall of colon.

- Automatic centerline extraction combining with easy selection UI to help fast path setup.
- Tagged-stool overlay on endoluminal and band view to enable to handle CT images with minimal preparations.
- Batch capture for reconstructed images related to lesions during the exam to report and send to clinicians.

Indications for Use: 21 CFR 807 92(a)(5)

XELIS™ is a software based device (utilizing PC hardware) for the display and visualization of 3D and 2D medical image data of the colon. Images and data are captured, stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Only DICOM, for presentation images will be captured for display and diagnosis. Analysis of images and diagnosis is not performed by the software but by Radiologists, Clinicians and referring Physicians as an adjunctive to standard radiology practices for diagnosis.

Digitized film screen images must not be reviewed for primary image interpretation. Mammographic images must not be interpreted using this system.

Technological Characteristics: 21 CFR 807 92(a)(6)

XELIS™ is a software device that does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for XELIS™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 2008

INFINITT Co. Ltd
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062-2096

Re: K082990
Trade/Device Name: XELIS™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 4, 2008
Received: November 6, 2008

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INFINITT

Medical Imagination

Indications for Use

510(k) Number (if known): K082990

Device Name: XELIS™

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082990